109TH CONGRESS
2D SESSION

H. R. 5102

To amend title XVIII of the Social Security Act to prohibit removal of covered part D drugs from a prescription drug plan formulary during the plan year once an individual has enrolled in the plan.

IN THE HOUSE OF REPRESENTATIVES

APRIL 5, 2006

Mr. BECERRA (for himself, Mr. DEFAZIO, Mr. SALAZAR, Mr. HONDA, Mr. JEFFERSON, Mr. KENNEDY of Rhode Island, Mr. BOUCHER, Mr. WEXLER, Mr. CARDOZA, Mr. MCGOVERN, Mr. MOLLOHAN, Mr. GENE GREEN of Texas, Mr. GRIJALVA, Mr. RANGEL, Mr. STARK, Mr. CONYERS, Mr. MCDERMOTT, Ms. HERSETH, Mr. HINCHEY, Mr. BROWN of Ohio, Mr. REYES, Mr. RUPPERSBERGER, Mr. LARSON of Connecticut, Mr. MCNULTY, Ms. MATSUI, Mr. COSTELLO, Mrs. MALONEY, Mr. MARSHALL, Mr. LEVIN, Ms. NORTON, Mr. INSLEE, Mr. LYNCH, Mr. DELAHUNT, Mr. OWENS, Mr. ORTIZ, Ms. SCHAKOWSKY, Mrs. NAPOLITANO, Mr. RYAN of Ohio, Mr. DOYLE, Mr. POMEROY, Mr. SCOTT of Virginia, Mr. BACA, Mr. SANDERS, Mr. CUMMINGS, Mr. OBERSTAR, Mr. PAYNE, Mr. GONZALEZ, Mr. EMANUEL, Mr. LANTOS, Mr. DOGGETT, Ms. WASSERMAN SCHULTZ, Mr. BRADY of Pennsylvania, Mrs. CAPPS, and Ms. MCCOLLUM of Minnesota) introduced the following bill; which was referred to the Committee on Energy and Commerce, and in addition to the Committee on Ways and Means, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned

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A BILL

To amend title XVIII of the Social Security Act to prohibit removal of covered part D drugs from a prescription drug plan formulary during the plan year once an individual has enrolled in the plan.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the "Medicare Drug Formulary Protection Act".

SEC. 2. REMOVAL OF COVERED PART D DRUGS FROM THE PRESCRIPTION DRUG PLAN FORMULARY.

(a) LIMITATION ON REMOVAL OR CHANGE OF COVERED PART D DRUGS FROM THE PRESCRIPTION DRUG PLAN FORMULARY.—Section 1860D–4(b)(3)(E) of the Social Security Act (42 U.S.C. 1395w–104(b)(3)(E)) is amended to read as follows:

"(E) REMOVING A DRUG FROM FORMULARY OR IMPOSING A RESTRICTION OR LIMITATION ON COVERAGE.—

"(i) LIMITATION ON REMOVAL, LIMITATION, OR RESTRICTION.—

"(I) IN GENERAL.—Subject to subclause (II) and clause (ii), beginning with 2006, the PDP sponsor of a prescription drug plan may not remove a covered part D drug from the plan formulary or impose a restriction or limitation on the coverage of such a drug (such as through the applica-

tion of a preferred status, usage restriction, step therapy, prior authorization, or quantity limitation) other than at the beginning of each plan year except as the Secretary may permit to take into account new therapeutic uses and newly covered part D drugs.

"(II) SPECIAL RULE FOR NEWLY ENROLLED INDIVIDUALS.—Subject to clause (ii), in the case of an individual who enrolls in a prescription drug plan on or after the date of the enactment of the Medicare Drug Formulary Protection Act, the PDP sponsor of such plan may not remove a covered part D drug from the plan formulary or impose a restriction or limitation on the coverage of such a drug (such as through the application of a preferred status, usage restriction, step therapy, prior authorization, or quantity limitation) during the period beginning on the date of such enrollment and ending on December 31

of the immediately succeeding plan year except as the Secretary may permit to take into account new therapeutic uses and newly covered part D drugs.

"(ii) EXCEPTIONS TO LIMITATION ON REMOVAL.—Clause (i) shall not apply with respect to a covered part D drug that—

"(I) is a brand name drug for which there is a generic drug approved under section 505(j) of the Food and Drug Cosmetic Act (21 U.S.C. 355(j)) that is placed on the market during the period in which there are limitations on removal or change in the formulary under subclause (I) or (II) of clause (i) if such generic drug is included in the formulary without any restriction or limitation placed on the coverage of such generic drug other than a restriction or limitation that would be placed on the coverage of the brand name drug during such period without the application of this subclause;

"(II) is a brand name drug that goes off-patent during such period;

"(III) is a drug for which the Commissioner of Food and Drugs issues a clinical warning that imposes a restriction or limitation on the drug during such period;

"(IV) has been determined to be ineffective during such period;

"(V) is a drug that the appropriate pharmacy and therapeutic committee determines, based on evidence from peer-reviewed research, to be unsafe or ineffective during such period; or

"(VI) is any other drug that satisfies any other requirement determined appropriate by the Secretary.

"(iii) NOTICE OF REMOVAL UNDER APPLICATION OF EXCEPTION TO LIMITATION.—The PDP sponsor of a prescription drug plan shall provide appropriate notice (such as under subsection (a)(3)) of any removal or change under clause (ii) to the

Secretary, affected enrollees, physicians, pharmacies, and pharmacists.".

(b) NOTICE FOR CHANGE IN FORMULARY AND OTHER RESTRICTIONS OR LIMITATIONS ON COVERAGE.—

(1) IN GENERAL.—Section 1860D–4(a) of such Act (42 U.S.C. 1395w–104(a)) is amended by adding at the end the following new paragraph:

"(5) ANNUAL NOTICE OF CHANGES IN FORMULARY AND OTHER RESTRICTIONS OR LIMITATIONS ON COVERAGE.—Each PDP sponsor offering a prescription drug plan shall furnish to each enrollee at the time of each annual coordinated election period (referred to in section 1860D–1(b)(1)(B)(iii)) for a plan year a notice of any changes in the formulary or other restrictions or limitations on coverage of a covered part D drug under the plan that will take effect for the plan year.".

(2) EFFECTIVE DATE.—The amendment made by paragraph (1) shall apply to annual coordinated election periods beginning after the date of the enactment of this Act.

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